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| 10/825,360 | 04/16/2004 | Fysh Dadd | COCH-0008-1 | 8103 |
| 22506 | 7590 | 07/21/2006 | EXAMINER | |
| JAGTIANI + GUTTAG 10363-A DEMOCRACY LANE FAIRFAX, VA 22030 | | | GEDEON, BRIAN T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3766 | |

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/825,360

Applicant(s)

DADD ET AL.

Examiner

Brian T. Gedeon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 33-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 21-32 is/are rejected.
- 7) ☒ Claim(s) 15-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/9/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 33-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12 June 2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 11, 14, and 22-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuzma (US Patent no. 6,321,125).

In regard to claims 1, 21 and 27, Kuzma discloses a cochlear stimulation system with a flexible carrier 204, 320, a plurality of spaced apart electrode contacts 200 formed on the carrier, at least one wire connecting each electrode contact 200 to a tissue stimulator, and a positioning member 310, shown in figures 7-9 and 15-17. The positioning member 310, radially extends outward from the surface of the carrier 204, 320, and enhances implantation of the carrier member 204, 320, col 7 lines 57-64. The Examiner contends that the structure of the positioning member 310 is sufficiently similar to that of the claimed holding member, even though it's intended use may be different from the claimed holding member.

In regard to claim 3, figures 15-17 show the positioning member 310 extending longitudinally along the length of the carrier member.

In regard to claim 4, the width of carrier member 204, 320, and the height of the positioning member 310 can be seen in figure 17.

In regard to claim 11, pair of wings 313 on the positioning member 310 serve as a support for connecting the positioning member 310 to the carrier member 204, 320, col 16 lines 31-36.

In regard to claim 14, in one embodiment of Kuzma, the positioning member 150, can be detachable from the carrier member 204, 320, col 11 lines 52-58.

In regard to claim 22, the distal tip of the flexible carrier 204, 320 has a ball-shaped electrode 315 attached to a wire conductor. The ball and the wire are made from platinum or other suitable material, col 16 lines 26-28. A practitioner of ordinary skill in the art would recognize platinum as a biocompatible electrical conducting material.

In regard to claim 23, figure 18 A shows the carrier member 320 and positioning member 310 being manipulated by the fingers of a practitioner.

In regard to claim 24, a guiding insert may be used to help manipulate the positioning member into place, col 8 lines 66-67 through col 9 lines 1-2.

In regard to claim 25, an insertion tool 340, facilitates implantation of the electrode array into the cochlea, col 17 lines 35-37.

In regard to claim 26, the insertion tool of claim 25, is an insertion tube 340. The insertion tube 340 contains a U-channel where the positioning member 310 is guided

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into place, and also contains a hook so that the electrode array 320 can be guided as well, col 17 lines 10-23.

In regard to claims 28 and 29, the carrier member 204, 320, is flexible, and can be made from any suitable silicon polymer or other suitable material, col 16 lines 24-26.

In regard to claim 30, figure 6A shows the implanted electrode array 10 with electrode contacts 200, implanted within the inner ear, and having assumed the natural spiral shape of the anatomy. Figure 19, depicts the carrier member 320 being inserted into the inner ear, as well as the carrier member 320 as having been straightened.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma (US Patent no. 6,321,125).

In regard to claim 2, the positioning member 150, 310 is located attached near the distal end of the carrier member 204, 320 in order to facilitate implantation of the electrode array 10 into the inner ear. Further, the positioning member 320 can be detachable, col 11 lines 52-58. It would have been obvious to one of ordinary skill in the art at the time the invention was made to locate the positioning member 150, 310 near

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the proximal end of the carrier member 204, 320, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japiske*, 86 USPQ 70.

Claims 5-10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma (US Patent no. 6,321,125) in view of Kuzma (US Patent no. 6,078,841).

In regards to the above claims, Kuzma '125 substantially describes the invention as claimed except for the dimensions of the holding member in relation to the carrier member. Kuzma '125 does describe some dimensions of the positioning member 150, 310, col 10 lines 23-39 and col 11 lines 59-67 through col 12 lines 1-59. Within this passage, the positioning member 150, 310 is described as tapes from its proximal end to the distal end. Kuzma '841 describes some other dimensions of a positioning member, col 7 lines 54-67 through col 8 lines 1-43. It would have been obvious to one of ordinary skill in the art at the time the invention was made to dimension a holding member in such a manner so as to correctly fit against an implantable lead, as well as to allow a tool or a physician's fingers to have an ample portion to grab hold of since where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma (US Patent no. 6,321,125) in view of Kuzma (US Patent no. 6,119,044).

In regard to claims 31 and 32, Kuzma '125 substantially describes the invention as claimed, except for the carrier member containing a lumen, which is adapted to

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receive a positioning stylet. Kuzma '044 describes an electrode array 10 with a flexible carrier body 13 containing a channel 11 that passes longitudinally therethrough, col 7 lines 16-19. The channel 11 has a diameter large enough to pass a positioning stylet 20 through, col 7 lines 35-39. The positioning stylet is composed of Nitinol, col 7 lines 39-40. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references to enhance the implantation of the electrode array into a patient's inner ear.

Allowable Subject Matter

Claims 15-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian T. Gedeon
Patent Examiner
Art Unit 3766



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

BTG